

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS**

**IN RE PHARMACEUTICAL INDUSTRY
AVERAGE WHOLESale PRICE
LITIGATION**

**MDL No. 1456
Master File No. 01-12257-PBS**

Judge Patti B. Saris

THIS DOCUMENT RELATES TO:

Magistrate Judge Bowler

*City of New York, et al. v.
Abbott Laboratories, et al.*
Civil Action No. 04-cv-06054 et al.

**DEFENDANT BOEHRINGER INGELHEIM ROXANE, INC.'S
OPPOSITION TO PLAINTIFFS' MOTION TO COMPEL DISCOVERY**

Plaintiffs' Motion to Compel Discovery from Defendant Boehringer Ingelheim Roxane, Inc ("Roxane"), is yet another attempt by Plaintiffs to expand inappropriately the breadth of this case and frustrate Judge Saris's "gateway" efforts to manage the enormous number of NDCs at issue and subject to discovery. Roxane's good faith position, shared by the majority of the defendants in this case, is that if a drug was subject to a Federal Upper Limit ("FUL") at some point during the relevant time period, but is not included as one of the nine FUL drugs chosen by the parties for expedited discovery pursuant to Case Management Order # 33, it is not properly part of discovery at this time. This position is grounded in the Court's prior rulings and is justified in light of the Court's attempt to narrow and refine the issues in this case. Moreover, Plaintiffs have not shown that they have been or will be prejudiced by Roxane's position. For these reasons, more fully explained below, Plaintiffs' Motion to Compel is meritless and should be denied.

BACKGROUND

Defendants' Motion to Dismiss And This Court's Related Orders

A key issue raised in Defendants' joint motion to dismiss Plaintiffs' First Amended Consolidated Complaint ("FACC") involved Plaintiffs' claims related to FULs and whether Plaintiffs had stated a claim with respect to their "FUL fraud" allegations. (*See* Docket Entry # 4376, Defendants' Joint Motion to Dismiss Plaintiffs' FACC, filed June 22, 2007) Defendants moved to dismiss Plaintiffs' claims with respect to drugs that were ever subject to a FUL because, *inter alia*, Plaintiffs did not and could not plead facts to show reliance on an individual defendant's published pricing nor could they plead facts to show causation based on such pricing for drugs subject to FUL reimbursement.

At oral argument on Defendants' motion, this Court noted that the FUL argument raised by Defendants was a "big issue outstanding" in the Court's mind (Ex. 1, 7/26/07 Tr. at 4:22-4:23) and that because there were "so many" drugs alleged to implicate "FUL fraud" it would make sense to engage in discovery based only on five drugs chosen by each side "rather than do discovery on these millions -- how many -- however many we end up with to find out what makes sense." (*Id.* at 28:13-28:17) Accordingly, the Court stated its desire to "fast track" discovery on FULs (*id.* at 31:6-31:7) because otherwise "[i]t's too many drugs. It's too expensive." (*Id.* at 33:5-33:6) For these reasons, the Court summarized, it made sense to "brief it before we do discovery on any other FULs." (*Id.* at 29:25-30:4)¹

On July 30, 2007 Judge Saris granted in part and denied in part Defendant's Joint Motion to Dismiss. The Court denied Defendants' motion with respect to drugs subject to a FUL, but, consistent with the statements made at oral argument, ordered that both Plaintiffs and Defendants

¹ The Court also noted its frustration with Plaintiffs' repeated attempts to broaden what is already an enormous case, noting that "every time I give you the opportunity, you expand it." (Ex. 1, 7/26/07 Tr. at 29:14-29:17)

“shall each select five drugs subject to FUL reimbursement,” and that “[d]iscovery shall proceed on those FUL drugs only.” (Order at ¶ 3) The Court stated that after expedited discovery on the selected FUL drugs, it will address the plaintiffs’ FUL claims on the selected drugs “on summary judgment with expert assistance and a more complete record.” (*Id.*)

On September 6, 2007, the Court entered CMO # 33 which laid out the procedures for the targeted discovery with respect to drugs subject to FULs. (*See* Ex. 2, CMO # 33) Within those delineated procedures, the Court ruled that the parties shall exchange their five selected drugs (the “Designated FUL Drugs”) and that although the parties may engage in discovery of the claims in the FACC “relating to FULs generally; ... there shall be no discovery on particular NDCs subject to and paid by New York Medicaid based on FULs other than those relating to the Designated FUL Drugs.” (*Id.* at ¶ 5(a)-(b)) The Court went on to note that discovery with respect to all other drugs appearing in the “new FACC Exhibits B-1 and B-3, and on all other issues in the FACC generally” to the extent not covered by the preceding paragraph detailing the FUL discovery procedures, shall proceed in accordance with the Federal Rules of Civil Procedure and the Court’s past Case Management Orders. (*See id.* at ¶ 7) On October 2, 2007, the parties’ exchanged their selected list of Designated FUL Drugs, resulting in a list of nine drugs, with one overlapping selection.

Plaintiffs’ Discovery Requests

On October 18, 2007, Plaintiffs served all Defendants with Plaintiffs’ First Request for the Production of Documents, which sought, among many other things, transactional data related to the “Subject Drugs,” defined therein as “any of the drugs or NDCs identified in the FACC, Revised Exhibit B.” (*See* Ex. 3, Plaintiffs’ First Request for the Production of Documents,

“Definitions” at ¶ 11)² In its Objections and Responses to these Requests, Roxane objected to the definition of “Subject Drugs” to the extent it “encompasses drugs for which discovery has been stayed pursuant to CMO # 33 entered by the Court on September 14, 2007.” (Ex. 4, Boehringer Ingelheim Roxane, Inc.’s Objections and Responses to Plaintiffs’ First Request for the Production of Documents, “General Objections” at ¶ 3) Subject to and without waiving all of its General and Specific Objections, Roxane agreed to produce, *inter alia*, responsive transactional data related to drugs subject to discovery under CMO # 33 for the relevant time period.

In a December 11, 2007 meet-and-confer phone call requested by Plaintiffs, counsel for Plaintiffs asked counsel for Roxane if it shared the position espoused by the majority of defendants that, based on CMO # 33, any NDC that appears in Revised Exhibit B which was ever reimbursed on the basis of a FUL is not properly the subject of discovery at this time. Roxane, through its counsel, indicated that this is its position with respect to those FUL drugs and further clarified that view in correspondence with Plaintiffs’ counsel. (*See* Ex. 5 12/12/07 Cicala Ltr. to Casazza; Ex. 6 12/20/07 Casazza Ltr. to Cicala) (“based on CMO # 33, we will not agree to produce responsive documents and data for Roxane NDCs (i) that were reimbursed on a FUL basis at any time during the relevant time period and (ii) are not included as one of the nine FUL drugs that are part of discovery at this time.”).

On December 21, 2007, Plaintiffs served³ Roxane with their Motion to Compel which seeks: (a) an order from the Court to direct Roxane to produce “all responsive documents and

² On November 6, 2007, Plaintiffs also served Plaintiffs’ Second Request for Production of Documents on Roxane and 14 other defendants related solely to the Designated FUL Drugs.

³ According to this Court’s docket, Plaintiffs did not file their motion, but did serve it via Lexis-Nexis File and Serve on December 21, 2007. After Roxane’s counsel notified Plaintiffs’ counsel of this error, the motion was filed on January 10, 2008. Plaintiffs also did not set forth on the face of the motion the anticipated response date as

data for Roxane NDCs in NY FACC Exhibit B with spreads greater than 30% where such NDCs were reimbursed based on Average Wholesale Price (“AWP”) (Ex. 7, Mem. in Support of Mot. to Compel Discovery from Defendant Boehringer Ingelheim Roxane Laboratories, Inc. at 1) and (b) payment for Plaintiffs’ attorneys fees and costs associated with their motion. (*See id.* at 3)

ARGUMENT

This Court should deny Plaintiffs’ Motion to Compel because Roxane’s position with respect to whether discovery shall proceed for drugs subject to a FUL during the relevant time period is justified by this Court’s prior rulings and the desire to maintain judicial economy of this case. Moreover, discovery is proceeding on the nine Designated FUL Drugs and all other drugs subject to discovery and Plaintiffs’ have not shown, nor could they, that they are prejudiced by Roxane’s position. Finally, Plaintiffs’ request for attorneys fees and costs should be denied because they have not and cannot demonstrate that Roxane’s position is anything other than “substantially justified.”

First, as noted, in response to Defendants’ Joint Motion to Dismiss, this Court concluded that Plaintiffs could proceed only as to those drugs which were reimbursed based on a FUL methodology for which Plaintiffs had made specific FUL-fraud allegations -- and even then, only as to a sampling of five drugs per side. In so doing, the Court, noted that the number of drugs at issue in this litigation was far greater than either the parties or any judicial system could reasonably adjudicate or address at once, and that in the face of such a “massive” case (Ex. 1, 7/26/07 Tr. at 17:18-17:19), there must be an effort towards “some constraint, not expansion.” (*Id.* at 11:18-11:19) This effort towards constraint was memorialized in this Court’s orders. In its July 30, 2007 Order, this Court specifically ruled that “[d]iscovery shall proceed on those

required by CMO # 8. Counsel for Roxane contacted Plaintiffs’ counsel requesting until January 11, 2008 to respond and Plaintiffs were agreeable.

[selected] FUL drugs only.” (Ex. 8 at ¶ 3) And in CMO # 33, in language ignored by Plaintiffs in their present motion, the Court specifically ruled that “*there shall be no discovery on particular NDCs subject to and paid by New York Medicaid based on FULs other than those relating to the Designated FUL Drugs.*” (Ex. 2, CMO # 33 at ¶ 5(b)) (emphasis added)

Plaintiffs nonetheless urge this Court to rule that they are entitled to discovery on certain portions of time that a drug which had been reimbursed on the basis of FUL at some time, may have been reimbursed on the basis of AWP at another time. But the case-management based rationale of CMO # 33 and Judge Saris’ order would be wholly undermined if Plaintiffs could proceed with immediate discovery on other drugs that indisputably did have a FUL in place, based solely on Plaintiff’s assertion that a FUL was not in place for *all* of the relevant time period.

Moreover, the rationale for seeking such additional discovery is subject to strong defenses. For example, imagine that CMS failed to publish a FUL for a drug during the third quarter of 1999, but had published a FUL during the five quarters before and after that period. Plaintiffs have not pleaded facts to show how they reasonably could have relied on published AWP’s in that isolated quarter, if they were already on notice of lower prices revealed in the FULs that were published during the given quarters beforehand. In the face of this type of threshold defense, piecemeal discovery as to piecemeal time periods makes little practical sense, serving only to burden the parties and the Court with exponentially more drugs to consider and more NDCs subject to discovery at a time when the Court repeatedly has attempted to streamline the issues and discovery in this case.

Second, there is no dispute as to the Designated FUL Drugs that are subject to the Court’s accelerated FUL discovery period, and discovery on those nine Designated FUL Drugs and all

other drugs reimbursed solely on AWP methodology, with an alleged spread of over 30%, is proceeding apace. Indeed, Roxane will shortly produce to Plaintiffs responsive data regarding close to 150 Roxane NDCs. In the face of what is sure to be a massive production, Plaintiffs would be hard-pressed to tell this Court with a straight face that they have been or will be prejudiced by postponement of discovery on some drugs that may never have to be done.⁴ On the other hand, Roxane would be unnecessarily burdened by Plaintiffs' position, which would produce ridiculous results. In effect, Roxane would be obligated to "slice and dice" its production on a single NDC between the time period that it was subject to a FUL (not discoverable per CMO # 33) and the time period that it was subject to AWP reimbursement (discoverable according to Plaintiffs). This would require a massive effort to determine when a FUL applied (or not) to a particular NDC and for what time periods.

Moreover, Plaintiffs' assertion that Roxane believes it has "no discovery obligations whatsoever" for non-Designated FUL Drugs is wrong (Mem. at 2): Roxane has never stated that discovery as to other FUL drugs should be barred for all time. Instead, Roxane will abide by the Court's prior rulings that discovery of other FUL'd drugs should be deferred until the accelerated FUL summary judgment framework established by this Court is complete. It is in the interests of the parties and the Court to do so, and Plaintiffs do not and cannot demonstrate any prejudice from sequencing discovery in this way.

Finally, Plaintiffs' request for an order requiring Roxane to pay Plaintiffs' counsel fees and costs associated with bringing Plaintiffs' motion should be denied. Even if this Court were

⁴ Even if a particular NDC has an alleged spread of over 30% in Plaintiffs' Revised Exhibit B to the FACC, if that same NDC was subject to a FUL during the relevant time period, Plaintiffs have not shown an over-30% spread for the time periods when a FUL was not in place and that NDC, based on a separate provision of CMO #33, would not be subject to discovery at this time. For example, if there are two years at issue and one is a year in which the NDC was subject to a FUL, it would be impossible to determine, based on Exhibit B, whether the allegation of an over-30% spread is a reflection of solely the year in which that NDC was subject to AWP reimbursement.

to grant Plaintiffs' Motion to Compel -- and it should not for all the reasons above -- an award of fees and costs is not warranted because Roxane's position is "substantially justified." Rule 37(a)(5)(A) of the Federal Rules of Civil Procedure provides, in pertinent part, that if a motion to compel is granted, the Court "must not order [payment of "reasonable expenses incurred in making the motion, including attorney's fees"] if: ... (ii) the opposing party's nondisclosure, response, or objection was substantially justified; or (iii) other circumstances make an award of expenses unjust." F.R.C.P. 37(a)(5)(A). "The standard of 'substantially justified' ... has been said to have been satisfied if there is a 'genuine dispute,' or 'if reasonable people could differ as to [the appropriateness of the contested action],'" *Notice v. DuBois*, 187 F.R.D. 19, 20 (D. Mass. 1999) (citing *Pierce v. Underwood*, 487 U.S. 552, 565 (U.S. 1988) (internal citations omitted)). Here, given the Court's aforementioned prior rulings with respect to FUL discovery in this case, and in keeping with the Court's obvious and necessary attempts to streamline discovery, Roxane's position is substantially justified. There is a genuine dispute between the parties with respect to this issue and it cannot be said that Roxane has been unreasonable in its position.

Pursuant to CMO # 8, Roxane proposes that Plaintiffs shall have until January 18, 2008 to file a reply brief, if any.

REQUEST FOR ORAL ARGUMENT

Pursuant to Local Rule 7.1(d), Roxane requests oral argument because it wishes to be heard and believes that a hearing will assist the Court in its determination of Plaintiffs' Motion to Compel.

CONCLUSION

For the foregoing reasons, Roxane respectfully requests that this Court deny Plaintiffs' Motion to Compel Discovery and their request for fees and expenses.

Respectfully submitted,

/s/ Brian P. Kavanaugh

Dated: January 11, 2008

Lauren O. Casazza
KIRKLAND & ELLIS LLP
Citigroup Center
153 East 53rd Street
New York, New York 10022-4611
Telephone: (212) 446-4800
Facsimile: (212) 446-4900

Helen E. Witt, P.C.
Brian P. Kavanaugh
KIRKLAND & ELLIS LLP
200 E Randolph Drive
Chicago, Illinois 60601-6636
Telephone: (312) 861-2000

*Attorneys for Boehringer Ingelheim Roxane,
Inc.*

CERTIFICATE OF SERVICE

I, Brian P. Kavanaugh, hereby certify that on January 11, 2008, I caused a true and correct copy of the foregoing, **DEFENDANT BOEHRINGER INGELHEIM ROXANE, INC.'S OPPOSITION TO PLAINTIFFS' MOTION TO COMPEL DISCOVERY**, to be served on all counsel of record in accordance with the Court's Case Management Order No. 2.

Dated: October 11, 2008

/s/ Brian P. Kavanaugh